

South Carolina Board of Pharmacy

P.O. Box 11927 • Columbia, SC 29211-1927

Phone: 803-896-4700 • Fax: 803-896-4596 • www.llronline.com/POL/Pharmacy/



NON-RESIDENT PHARMACY PERMIT APPLICATION

For Board Use Only	
Date Paid	
Amount Paid	
Check #	

Pharmacist-in-charge for the applicant must attend an Application Review Committee meeting at the Board's office. Applicants will be notified by mail of the next available meeting once the application is processed. Return completed application along with the **non-refundable \$300 permit fee** and requested documents. Additional documentation is required of compounding pharmacies (see attached list). Using false, fraudulent, forged statement or document, or committing a fraudulent, deceitful or dishonest act or omitting a material fact in obtaining licensure is grounds for discipline under §40-1-110(1)(a).

- ☐ New Permit
☐ Change to Existing Permit (Permit # _____)
 ☐ Change of Ownership
 ☐ Change of Name
 ☐ Change of Location

Federal Employer Identification Number (FEIN): _____

Name of Pharmacy _____

Street Address

City _____ State _____ Zipcode _____

Phone# Fax# Resident State License#:

Name of Corporation

Office Address

Pharmacy Owned By: ☐ Individual ☐ Partnership ☐ Corporation ☐ LLC

IF CHANGE IN OWNERSHIP OR NAME:

Previous Owner/Name of Pharmacy	SC Permit Number
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Pharmacist-in-Charge: _____ License# _____

Residence Address: _____

<i>Street address</i>	<i>City</i>	<i>State</i>	<i>Zipcode</i>
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PHARMACISTS FULL TIME (use separate sheet if necessary)	LICENSE NUMBER
PHARMACISTS PART TIME	LICENSE NUMBER
PHARMACY TECHNICIANS	LICENSE NUMBER

What is the daily working ratio of pharmacist to pharmacy technician? _____

Do you fill prescriptions via the internet? ☐ YES ☐ NO

If YES, is there a valid patient-practitioner relationship within the state of South Carolina? ☐ YES ☐ NO

SC Medical Practice Act Section 40-47-113. Establishment of physician-patient relationship as prerequisite to prescribing drugs; unprofessional conduct. [SC ST SEC 40-47-113]

(A) It is unprofessional conduct for a licensee initially to prescribe drugs to an individual without first establishing a proper physician-patient relationship. A proper relationship, at a minimum, requires that the licensee make an informed medical judgment based on the circumstances of the situation and on the licensee's training and experience and that the licensee:

(1) personally perform and document an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan;

(2) discuss with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options; and

(3) ensure the availability of the licensee or coverage for the patient for appropriate follow-up care.

(B) Notwithstanding subsection (A), a licensee may prescribe for a patient whom the licensee has not personally examined under certain circumstances including, but not limited to, writing admission orders for a newly hospitalized patient, prescribing for a patient of another licensee for whom the prescriber is taking call, prescribing for a patient examined by a licensed advanced practice registered nurse, a physician assistant, or other physician extender authorized by law and supervised by the physician, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.

(C) Prescribing drugs to individuals the licensee has never personally examined based solely on answers to a set of questions is unprofessional.

Pharmacy website address: _____

What are the pharmacy hours of operation? _____

What are the hours a pharmacist is available? _____

Does your pharmacy perform central fill? ☐ YES ☐ NO

When was your last Board of Pharmacy inspection? _____
(Attach a copy of the inspection report)

Do you currently have a South Carolina-licensed pharmacist on staff? ☐ YES ☐ NO

If YES, provide name and license number: _____
Name SC license number

When did you last review and/or revise standard operating policy and procedures? _____

Date on which your pharmacy began mail order dispensing: _____

Date on which your pharmacy began dispensing to South Carolina patients: _____

Approximate number of South Carolina patients served annually: _____

**ATTACH YOUR PHARMACY LABEL HERE.
LABEL MUST INCLUDE A TOLL-FREE PHONE NUMBER
FOR USE BY S.C. RESIDENTS.**

COMPOUNDING

Does your pharmacy do compounding? ☐ YES ☐ NO (skip compounding questions 1-8)

Sterile compounding ☐ YES ☐ NO

Non-sterile compounding ☐ YES ☐ NO

Are you registered as a 503B outsourcing facility with the FDA? ☐ YES ☐ NO

If yes, has your facility been inspected for compounding by the FDA?

[] YES Date of inspection_____ [] NO

Was a Form 483 issued? ☐ YES (attach a copy of the form) ☐ NO

COMPOUNDING QUESTIONS

Additional documentation required (see attached lists)

1-Do you have PCAB accreditation? ☐ YES (expiration date of accreditation _____)
☐ NO

2- Have you attempted PCAB accreditation? ☐ YES Status of accreditation: _____

☐ NO Reason:_____

3-Do you use an independent lab or qualified individual for end product testing?

[] YES Provide name and address: _____

☐ NO

4-Do you use an independent lab or qualified individual for routine environmental testing of hood, ante room and clean room?

[] YES Provide name and address: _____

☐ NO

5-Do you provide non-patient specific compounded products? ☐ YES ☐ NO

6-Do you sell compounded products to wholesalers? ☐ YES ☐ NO

If YES, please provide wholesalers name and address: (attach separate sheet if necessary)

[illegible]

Name	Address
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7-Do you compound preparations that are copies of FDA-approved products? ☐ YES ☐ NO

If YES, explain the circumstances: _____

8-Do any of the preparations you compound contain ingredients that were withdrawn

or removed from the market for reasons of safety? See www.fda.gov ☐ YES ☐ NO

If YES, identify and explain _____

LIST BELOW THE NAME AND REQUIRED INFORMATION FOR ALL OWNERS, PARTNERS, CORPORATE OFFICERS, ADMINISTRATORS AND DIRECTORS (use additional sheet if necessary)

<u>NAME</u>	<u>TITLE</u>	<u>RESIDENCE ADDRESS</u>	<u>% OWNERSHIP</u>

TO THE BEST OF YOUR KNOWLEDGE, HAS THE APPLICANT EVER:

1. Had a permit disciplined, denied, refused or revoked for violations of any pharmacy laws or drug laws in South Carolina or any other state? ☐ YES ☐ NO

a. Is there any pending disciplinary action? ☐ YES ☐ NO

2. Been charged, convicted, fined or entered in a plea of guilty or nolo contendere in any criminal prosecution, felony or misdemeanor in South Carolina or any other state, or in a United States court for

a. any offense relating to drugs, narcotics, controlled substances, or alcohol, whether or not a sentence was imposed? ☐ YES ☐ NO

b. any offense involving the practice of pharmacy, or relating to acts committed within a pharmacy or drug distributor setting or incident to pharmacy practice, whether or not a sentence was imposed? ☐ YES ☐ NO

c. any offense involving fraud, dishonesty or an act of violence whether or not a sentence was imposed? ☐ YES ☐ NO

d. For any offense involving moral turpitude whether or not a sentence was imposed? (if you are unsure, check "yes") ☐ YES ☐ NO

3. Have you ever:

a. Had an application for a pharmacy; pharmacist license, permit or certificate; or a technician license or registration denied, refused or revoked in South Carolina or any other state or country? ☐ YES ☐ NO

b. Had disciplinary action taken against you, a pharmacy or drug distributor facility you owned, or a pharmacy or drug distributor facility where you were employed, by the Board of Pharmacy (or its equivalent) in South Carolina or any other state or country? ☐ YES ☐ NO

4. Violated the drug laws, rules, statutes and/or regulations of South Carolina or any other state or country? ☐ YES ☐ NO

****If you answered "yes" to any part of the above section, please provide a detailed explanation, attach copies of applicable court documentation and submit the documentation to the SC Board of Pharmacy. Include the city and state where the offense(s) occurred.**

This is to certify that I have read and approved the foregoing and the statements are true and correct to the best of my knowledge and belief; that I will comply with the Code of Laws of the South Carolina Pharmacy Practice Act and that I understand I am responsible for any violation(s) occurring during my tenure.

_____	Subscribed and sworn to before me this date:
Print name of Pharmacist-in-Charge	
_____	_____
Signature of Pharmacist-in-Charge	Notary Public
Date: _____	State _____
_____	My Commission Expires: _____
Email address of Pharmacist-in-Charge	

I declare that the foregoing statements are true and correct to the best of my knowledge and belief; the permit applied for is to cover only the pharmacy indicated above and at the location specified; and that I will comply with the Code of Laws of the South Carolina Pharmacy Practice Act.

_____	Subscribed and sworn to before me this date:
Name and Title of Permit Holder	
_____	_____
Signature of Permit Holder	Notary Public
Date: _____	State _____
_____	My Commission Expires: _____
Email address of Permit Holder	

Controlled substance information: Non-resident pharmacies permitted by the SC Board of Pharmacy who dispense controlled substances are required to obtain a South Carolina Controlled Substances Registration from the SCDHEC-Bureau of Drug Control. Access the application via the website at www.dhec.sc.gov/Health/FHPF/DrugControlRegisterVerify/NewRegistrations/

All SC-permitted non-resident pharmacies must register with the SCDHEC-Bureau of Drug Control Prescription Monitoring Program. If you do not dispense controlled substances, you must request an exemption from reporting requirements. Contact PMP at scripts@dhec.sc.gov or (803) 896-0688.

Send completed application and non-refundable fee payable to SCDLLR Board of Pharmacy to:	
<u>Mailing address:</u>	<u>Overnight/physical address</u>
PO Box 11927	110 Centerview Dr, Suite 201
Columbia, SC 29210	Columbia, SC 29211-1927

Checklist:

- ___ copies of all state pharmacy licenses held by your pharmacy
- ___ copy of your Policy and Procedure for shipping refrigerated products
- ___ state controlled substance license
- ___ DEA registration
- ___ inspection report
- ___ compounding requirements ****If your pharmacy compounds, even though you do not plan to ship sterile/non-sterile compounds into SC, you must still submit all compounding information. South Carolina does not have a separate permit for sterile or non-sterile compounding.**
- ___ copy of accreditation certificates
- ___ photographs of the following areas:
 - 1-exterior of the building in which the pharmacy is located to include identifiable parts of adjacent buildings in any
 - 2-front end of the pharmacy to include consulting area and drop-off/pickup
 - 3-compounding area
 - 4-work area

- **The state of South Carolina does not allow central filling of prescriptions, therefore each pharmacy must receive the prescriptions from the practitioner or authorized agent. A patient cannot fax or scan a prescription to the pharmacy, therefore the patient would have to mail the prescription to the pharmacy.**

SECTION 40-43-86 (F) A prescription drug order must be issued for a legitimate medical purpose by a practitioner acting within the course of legitimate professional practice. The prescription drug order must be received at the pharmacy as it was originally transmitted. Each prescription drug order becomes part of a permanent record and must be readily retrievable. The institutional pharmacist must review the physician's drug order, or a direct copy, prior to dispensing any drug (except for emergency use). Electronically transmitted prescription drug orders shall meet these requirements:

- (1) must be sent only to a pharmacy of the patient's choice;
- (2) must be received at the pharmacy as it was originally transmitted by facsimile or computer and shall include the name and address of the practitioner, the phone number for verbal confirmation, the time and date of transmission, and the name of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law;
- (3) a pharmacist may dispense prescription drug orders transmitted electronically only when transmitted by an authorized practitioner or his designated agent;
- (4) the pharmacist shall exercise professional judgment regarding the accuracy or authenticity of the transmitted prescription drug order consistent with existing federal or state laws and regulations;
- (5) any alterations of electronic transfer of a prescription drug order or information constitutes an unlawful act which will be prosecuted by the Attorney General of this State;
- (6) the prescribing practitioner may authorize his agent to transmit a prescription drug order orally or electronically to the pharmacy provided that the identity of the transmitting agent is included in the order.

- **Compounded medications cannot be re-sold, therefore the compounded medications must be sent and billed to the patient or sent to a physician/facility to be administered on site.**

SECTION 40-43-86 (CC)(2) (e) (e) Pharmacists may not offer compounded medications to other pharmacies for resale; however, pharmacists may compound products based on an order from a practitioner for use by practitioners for patient use in institutional or office settings. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services, e.g., chemicals, devices, and information, when requested; however, they may not solicit business by promoting to compound specific drug products, e.g., like a manufacturer;

- **The pharmacy must keep all records and a pharmacist must be present during all compounding functions.**

SECTION 40-43-86 (N)(1) A facility located outside this State, whose primary business is mail order prescription service, shall have a permit issued by the board to ship, mail, or deliver a controlled substance or dangerous drug or device into this State pursuant to a prescription of a licensed practitioner. The facility shall report to the board:

(a) information on the location, names, and titles of all principal corporate officers and pharmacists who are dispensing controlled substances or dangerous drugs or devices to residents of this State. The report must be updated annually and within thirty days of a change of permit holder or pharmacist-in-charge;

(b) that it complies with the applicable laws for operation in the state in which it is located and with the provisions of this section. The facility shall have a valid unexpired license, permit, or registration in compliance with the laws of the state in which it is located and must be constantly under the personal and immediate supervision of a licensed pharmacist. The facility shall submit to the board with its initial application and with each renewal application a copy of its most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located. These inspections are deemed to meet all inspection requirements contained in this chapter;

(c) that it maintains its records of controlled substances or dangerous drugs or devices dispensed to patients in this State so that the records are readily retrievable.

- **If the state in which the pharmacy is located does not have a pharmacist to auxiliary personnel ratio, a pharmacist is not allowed to supervise more than two pharmacy technicians at one time.**

SECTION 40-43-86 (N)(3) If the state in which the facility is located does not establish, by statute or regulation, a ratio describing the number of auxiliary personnel that a pharmacist may supervise, or otherwise define the role of the pharmacist in the compounding and dispensing of prescription drugs, then that facility may not allow a pharmacist to supervise more than two pharmacy technicians at any time in the compounding and dispensing of prescription drugs.

- **The pharmacy label must contain a toll-free number and have a pharmacist available during its regular house of operation, but not less than 6 days or 40 hours a week.**

SECTION 40-43-86 (N)(4) A pharmacy, as described in this section, during its regular hours of operation but not less than six days or forty hours a week, shall provide a toll-free telephone service to facilitate communication between patients in this State and a pharmacist at the pharmacy who has access to their records. This telephone number must be printed on a label affixed to the container for the substance, drug, or device.

NON-RESIDENT PHARMACY

NON-STERILE COMPOUNDING REQUIREMENTS

****All information will be kept confidential by the Board**

- A. Compounding Policies and Procedures specific to your facility**
- B. List of products to include top 10 compounded products with Beyond Use Dating**
- C. Diagram of Compounding Area**
- D. Formulas for top 10 Compounded Products**
- F. Copy of compounding log and compounded product formula worksheets for last two weeks**
- G. Copy of Final Product Label**
 - 1. Prescription Label**
 - 2. Non-Patient Specific Compounds**

If files are large, they may be submitted on a CD or USB jump drive.

NON-RESIDENT PHARMACY

STERILE COMPOUNDING REQUIREMENTS

****All information will be kept confidential by the Board**

- A. Compounding Policies and Procedures specific to your facility**
- B. List of top ten CSPs including beyond use dating. Include reasoning for BUD assigned.**
- C. Diagram of Sterile Compounding Area**
- E. Copy of last inspection, by qualified individual, of hoods, buffer, clean and ante areas including ISO classification, particle counts and microbiology**
- F. Formulas for top 10 non-sterile to sterile compounded products**
- G. Logs for last full month to include:**
 - 1. cleaning of all areas used in sterile compounding process**
 - 2. pressure differential monitoring**
 - 3. environmental testing of sterile compounding area**
 - 4. logs for repackaged sterile compounded products**
- H. Copy of final product label**
 - 1. minibag**
 - 2. large volume**
 - 3. TPN**
 - 4. syringe**
 - 5. vial**